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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation, BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and BECTON DICKINSON AND COMPANY, a New Jersey corporation,	:	Case No. 94-105 RRM
Plaintiffs,	:	
v.	:	
CELLPRO, INC., a Delaware corporation,	:	
Defendant.	:	

DECLARATION OF DR. MICHAEL BISHOP

DECLARATION OF DR. MICHAEL BISHOP

I, Michael Bishop, M.D., hereby declare that:

1. I am an Associate Professor in the Department of Medicine of the University of Nebraska Medical Center. Attached hereto as Exhibit A is a copy of my Curriculum Vitae.

2. I am thoroughly familiar with the capabilities of CellPro's CEPRATE® SC stem cell concentrator, based on: (a) having extensively read the scientific and technical literature about the capabilities of the device; (b) having regularly worked with the device in the course of clinical trials and studies over the past two (2) years; (c) having performed stem cell transplant procedures on at least fifteen (15) patients using suspensions prepared with the device; and (d) being currently involved in further clinical studies in pursuit of new therapies that utilize the CEPRATE® SC stem cell concentrator.

3. I have used the CEPRATE® SC device in CellPro-sponsored randomized clinical trials for multiple myeloma patients undergoing autologous stem cell transplantation procedures using peripheral blood processed by the CEPRATE® SC device.

4. I have also been extensively involved in an ongoing randomized trial sponsored by a grant from the National Heart, Lung and Blood Institute using the CEPRATE® SC device. In that clinical trial we are comparing the efficacy of unmanipulated and T-cell depleted stem cell suspensions in allogeneic transplantation procedures using CD34+ cells from bone marrow processed by the CellPro device. There, the CellPro device is used as a part of our T-cell depletion (elutriation) process.

5. I am also involved in an ongoing clinical study of metastatic breast cancer focusing on tumor contamination of stem cell products used in autologous transplantation of peripheral blood processed by the CellPro device. In that study, the CellPro device is utilized to obtain CD34+ cell suspensions to minimize the risk of contamination with tumor cells. We plan to apply for a peer-reviewed grant based on the data from that study.

6. In the future, I also plan to use the CellPro device for allogeneic transplantation procedures using peripheral blood processed by the CellPro device.

7. In my view, the CellPro CEPRATE® SC device presents a major practical advancement in performing transplantation procedures from the standpoint of reliability, ease of use and technology. The CellPro device provides a reproducible and practical technology for T-cell depletion and purging in stem cell recovery. In my experience, I have found alternative techniques for accomplishing this to be laborious. Furthermore, the CellPro device lends itself for further novel applications in gene therapy.

8. I find it important that the CellPro CEPRATE® SC device is the only FDA-approved stem cell concentration device, because I can use it for other clinical protocols as I deem appropriate without having to go through the cumbersome FDA approval process that would be the case with an unapproved device. Indeed, the fact that the CellPro device is FDA-approved makes it easier (in terms of cutting down the amount of red tape and institutional resistance) to get an experimental protocol approved by the FDA and/or the hospital's or university's approval committee if at least the stem-cell-enrichment and transplant step is done with an FDA-approved device.

9. The patients that undergo therapy under our clinical studies come from both a volunteer pool as well as being recruited. The availability of the CellPro technology is important to us because it hopefully encourages the patients to come to our center for treatment.

10. As a practical matter, the fact that we can tell a patient that a particular experimental procedure is performed by and FDA-approved device, would in some ways give the patient the comfort level to make a decision whether to undergo an experimental treatment.

11. Accordingly, I believe there is a compelling public interest in the continued availability, and access to, the CellPro CEPRATE® SC device. Without the CellPro device, our clinical work would be set back by up to two (2) years. Further, T-cell depleted allogeneic peripheral blood transplant procedures would be made more difficult. If the CellPro device is made unavailable, we would have to discard data of our clinical studies already in progress, and start over. We would further have to retrain staff to use a new device, and must reapply for FDA and institutional clearance to conduct our clinical studies with an unapproved device. Above all, I would not be certain that a substitute device would work as well for my purposes.

12. For some patients, the CellPro device represents the only optimal and quick treatment other than traditional treatments (such as PCT transplants). For example, one of my transplant patients, who had an unrelated-matched bone marrow transplant, had a graft failure. The original donor refused further harvest. We had to use a related-mismatched donor's blood (in that case, the patient's father) and performed the T-cell

depletion step with the CellPro device. That patient grafted successfully. Without the CellPro device, that patient would have been left with no remedy other than the traditional remedies.

13. I believe the availability of the CellPro device has opened up new and novel fields of treatment such as those that may be categorized under the general rubric of gene therapy in which CD34+ cells are selected by the CellPro device for transfection. Particular examples of gene therapy applications that are facilitated by the CellPro device include: suicide T-cells, replacement of deficient genes and chemo-resistant genes.

I further declare under penalty of perjury that the foregoing is true and correct.

Executed at Omaha, Nebraska, this 16 day of April, 1997.

Michael Bishop, M.D.

CURRICULUM VITAE

PERSONAL:

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EDUCATION:

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POST-DEGREE TRAINING:

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1986 - 1988 — Residency, Internal Medicine
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